

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

In re: PHARMACEUTICAL INDUSTRY	:	SUBPOENA IN A CIVIL CASE
AVERAGE WHOLESALE PRICE	:	MDL NO. 1456
LITIGATION	:	
	:	Civil Action No. 01-12257-PBS
	:	
	:	Judge Patti B. Saris
	:	(case pending in D. Mass.)
THIS DOCUMENT RELATES TO THE	:	
CONSOLIDATED CLASS ACTION	:	

**NON-PARTY NATIONAL HERITAGE INSURANCE COMPANY'S  
MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO COMPEL  
PRODUCTION OF DOCUMENTS AND WITNESSES PURSUANT TO  
SUBPOENAS, AND IN SUPPORT OF ITS CROSS-MOTION  
TO QUASH SUBPOENAS**

On October 27 and 28, 2005, Aventis Pharmaceuticals, Inc. ("Aventis"), on behalf of itself and all other Track Two Defendants ("Defendants"), served two subpoenas on non-party National Heritage Insurance Company, Inc. ("NHIC") ordering the production of documents and the testimony of witnesses at a Rule 30(b)(6) deposition. However, the October 27 subpoena for production of documents is unusually invasive and extraordinarily burdensome.<sup>1</sup> Indeed, the Defendants' subpoena seeks a dizzying array of 27 discrete

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<sup>1</sup> The United States of America filed its Opposition to Aventis' Motion to Compel, and a Cross-Motion to Quash the October 28, 2005 deposition subpoena. The United States' brief argues, *inter alia*, that NHIC is a Medicare contractor and the testimony sought concerns information gathered for the purpose of processing Medicare Part B claims. Accordingly, Defendants must follow the regulations set forth at

categories of documents, relating to at least 130 different “subject drugs,” from a period of more than eight years, spanning from January 1, 1998 through the present. Many of these documents are on paper files, not stored electronically, and therefore must be compiled manually, a task which can only be accomplished by searching through thousands of paper files stored in NHIC’s offices, as well as its warehoused documents.

The task of responding to these onerous requests is complicated further by the fact that many of the records Defendants seek contain medical records that are individually identifiable. NHIC is required by the Health Insurance Portability and Accountability Act (“HIPAA”) to keep such records confidential. Thus, producing the records sought by Defendants would require a separate and additional analysis by legal counsel. As set forth in the accompanying affidavit, compliance with Defendants’ subpoena for the production of documents will cost hundreds of thousands of dollars. *See* Affidavit of Deborah A. Johnson (“Johnson Aff.”) ¶ 7 (attached as Exhibit A).

Finally, Defendants do not even argue that the value of the information to the Defendants outweighs the burden on NHIC of complying with their production requests. Indeed, counsel for Aventis emailed NHIC on January 19, 2006 with a revised, and substantially reduced, request for production of documents. Apparently, Defendants require

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45 C.F.R. Part 2 in order to request testimony and documents. As argued in the United States’ brief, Defendants have not followed those regulations. NHIC joins the United States’ Opposition and Cross-Motion to Quash the October 28, 2005 deposition subpoena, and will not restate those arguments here.

only the information sought in its e-mail request, and do not need all of the documents originally sought in its October 27, 2005 subpoena. For all of these reasons, this Court should deny Defendants' Motion to Compel, and grant NHIC's Motion to Quash. In the alternative, this Court should order Defendants to pay all reasonable costs associated with complying with Defendants' request for document production, including reasonable attorneys' fees.

### **BACKGROUND**

#### **A. Defendants Serve Unduly Burdensome Subpoena for Production of Documents on NHIC**

On October 27, 2005, Defendants served on NHIC, which is not a party to the underlying litigation, a subpoena seeking production of 27 discrete categories of documents, over a time span of more than eight years, from January 1, 1998 through the present, relating to at least 130 different drugs. *See* Notice of Subpoenaed Deposition of NHIC, October 27, 2005 (attached as Exhibit B). The information sought by Defendants includes, *inter alia*, the following categories of documents:

- All documents relating to claims processing policies and procedures for the 130 "subject drugs" identified by Aventis, including "methodologies considered, rejected, or implemented for calculating Medicare Part B" reimbursement rates;
- All communications to or from providers, benefit consultants, or auditors regarding Medicare Part B reimbursement, payment, or prices for any of the 130 "subject drugs";

- All communications between NHIC and the Centers for Medicare and Medicaid Services (“CMS”) or the Health Care Financing Administration (“HCFA”) regarding Medicare Part B reimbursement, payment, or prices for any of the 130 “subject drugs”;
- All documents reflecting that the submitted charges of health care providers for Medicare Part B beneficiaries were not equal to the statutory average wholesale price (“AWP”) ceiling;
- All documents relating to Medicare Part B reimbursement payments to providers that were less than the statutory AWP ceiling for any of the 130 “subject drugs”;
- All documents reflecting that any Medicare Part B provider reimbursement payments for any of the 130 “subject drugs” were not based in on AWP; and
- All documents relating to the use of a health care common procedure coding system (“HCPCS”) code for any of the 130 “subject drugs.”

Counsel for NHIC served and filed its objections to the subpoenas on November 9, 2005, the day after it received notice of Aventis’ production request. *See* NHIC Objections to Subpoena (attached as Exhibit C).

**B. NHIC Attempts to Resolve Dispute Regarding Subpoena for Production of Documents**

Aventis’ Motion to Compel states that, after NHIC lodged its objections, “NHIC has all but refused to discuss the matter any further.” Aventis’ Motion to Compel at 2. Nothing could be further from the truth. Following receipt of the subpoena for document production, counsel for NHIC engaged in substantial discussions with counsel for Defendants, and

pointed out that NHIC had previously produced a voluminous number of documents. Based on these discussions, NHIC reasonably believed the current subpoena would be withdrawn following Defendants' review of documents that NHIC had already produced. Thus, on November 22, 2005, counsel for NHIC e-mailed counsel for Aventis to register his "understanding that at the present time, with our objection on file, there is nothing further National Heritage needs to do. [T]he request for documents will be discussed by you with national counsel *to determine what may be needed.*" See November 22, 2005 e-mail (attached as Exhibit D). Counsel for Aventis did not respond to this e-mail.

However, approximately two months later, Aventis abruptly resumed its pursuit of certain documents from NHIC. On January 19, 2006, Aventis e-mailed NHIC with an amended and streamlined request for document production, which included only four categories: (1) Medicare B pricing records; (2) electronic claims data; (3) records reflecting whether charges submitted by providers were based on AWP, and the frequency with which the submitted charges deviated from the AWP ceiling; and (4) surveys concerning physician acquisition costs for the subject drugs. See January 19, 2006 e-mail (attached as Exhibit E). Even though the modified document production request was considerably less burdensome than the original production request, NHIC was obliged to seek guidance from CMS as to the propriety of producing records and data NHIC generated while carrying out its Medicare carrier contractual responsibilities. In addition, NHIC was concerned that the documents

contained personal patient health information. *See* January 24, 2006 e-mail (attached as Exhibit F).

On February 1, 2006, counsel for NHIC e-mailed Aventis to indicate that NHIC was coordinating its responses to the modified discovery request with the United States Department of Justice, and evaluating its obligations to protect the privacy of patient records under HIPPA. *See* February 1, 2006 e-mail (attached as Exhibit G). On March 8, 2006, moreover, counsel for the United States Department of Health and Human Services ("HHS") contacted Defendants to warn that their subpoena for deposition testimony was premature, because they had neglected to follow HHS' *Touhy* regulations set forth in the Code of Federal Regulations. *See* March 8, 2006 Letter (attached as Exhibit H). With regard to Defendants' revised request for documents, HHS counsel indicated that "we are in the process of reviewing the requests . . . . Any response to the document request will entail a privilege review once NHIC locates and identifies responsive documents. *We will endeavor to provide an expedited review of documents which NHIC identifies as responsive to the subpoena.*" However, before NHIC could resolve these outstanding issues, Aventis filed its motion to compel.

**C. Compliance with Full Extent of Defendants' Subpoena for Production of Documents Would Impose Significant Burden on NHIC, Which Is Not a Party to This Litigation**

As stated in the Affidavit of Deborah A. Johnson, who is the full-time Massachusetts Systems Support Manager for the Medicare Part B Carrier account, compliance with Defendants' request for production of documents would impose a substantial burden of time and expense on NHIC, which is not a party to this litigation. *See* Affidavit of Deborah A. Johnson ("Johnson Aff.") ¶ 2. According to Ms. Johnson's Affidavit, the process of identifying, reviewing, redacting, and producing all responsive documents "will be extremely costly and burdensome for NHIC" for several reasons. *Id.* ¶ 3.

First, NHIC would have to search through its vast repository of paper documents in its offsite storage facility to identify responsive documents. *Id.* ¶ 4(a). NHIC presently maintains between 30,000 and 35,000 boxes of paper documents in storage at an offsite facility, all of which could contain potentially responsive material for the time frame specified in the Defendants' subpoena. *Id.* ¶ 4(a). These documents are archived with brief descriptions of their contents in paper logs that must be searched manually. *Id.* Once boxes identified for further review are pulled from storage, it will take additional time to examine their contents to ascertain whether they are responsive to the subpoena. *Id.* It is presently impossible to determine exactly how much time would be required for NHIC employees to complete this review. However, assuming that one FTE can review an average of two boxes

of documents in an 8-hour day, it would take 500 FTE-days to review even 1,000 boxes to locate potentially responsive documents. *Id.* Depending on how many of the 30,000 to 35,000 boxes are determined to contain potentially reviewable information, this effort could consume thousands of FTE-days. *Id.*

Second, NHIC would have to search through the 18 months of data regarding claims, payments, and other services that it maintains online. *Id.* ¶ 4(b). Older data from the mainframe is stored on storage tapes, *i.e.* magnetic tape cartridges. *Id.* To search the mainframe and storage tapes for potentially responsive documents would require the creation of several computer programs. *Id.* The creation of each such program to identify and recover responsive documents will take hundreds of hours for which NHIC must pay an hourly rate of more than \$100 plus CPU charges. *Id.* Once potentially responsive documents are printed, it will take additional time to examine their contents to ascertain whether they are responsive to the subpoena. *Id.*

Third, NHIC would have to review hundreds of thousands of e-mail messages, associated attachments, and electronic files. *Id.* ¶ 4(c). These electronic files are maintained by NHIC employees and contract workers on site at NHIC's main Massachusetts office in Hingham, Massachusetts, and at a few other sites where EDS personnel working on the NHIC Massachusetts accounts are stationed. *Id.* These electronic files are maintained on servers, in employees' hard drives, and in storage media such as CD's and floppy disks. *Id.*



To retrieve potentially responsive documents, the affected employees and contract workers will be required to search and deliver all possibly responsive documents for review. *Id.* Once potentially responsive documents are printed, it will take additional time to examine their contents to ascertain whether they are responsive to the subpoena. *Id.* Assuming that one FTE can review an average of 5,000 pages per day, it will take approximately 100 FTE-days to review only 500,000 pages of electronic files for copying and production. *Id.* The number of responsive files requiring review may far exceed that figure. *Id.*

Fourth, NHIC would have to retrieve potentially responsive documents from its in-house files. *Id.* ¶ 4(d). These files include approximately 175 large, five-drawer file cabinets which contain an average of 10,000 pages per file cabinet, plus smaller files maintained by individual NHIC employees. *Id.* Once potentially responsive documents are gathered, it will take additional time to examine their contents to ascertain whether they are responsive to the subpoena. *Id.* Again, assuming that one FTE can review an average of 5,000 pages per day, it would require approximately two FTE-days to review each file cabinet for responsive documents.

Fifth, after locating responsive documents, NHIC will have to redact any privileged information and Protected Health Information ("PHI") that NHIC is required to remove prior to disclosure pursuant to HIPAA. *Id.* ¶ 5. Because many of these documents will

contain extensive amounts of PHI, that undertaking will require extensive time and resources to accomplish. *Id.*

Based on the foregoing, compliance with Defendants' request for production of documents will cost hundreds of thousands of dollars in labor alone to gather, review, redact, and produce all of the documents requested in the subpoena. *Id.* ¶ 6. In addition, NHIC would bear additional costs for Bates labeling, photocopying, electronic scanning, creating key-word indexing and retrieval capabilities, and shipping. *Id.*

### ARGUMENT

Rule 45(c)(1) requires all counsel preparing and serving subpoenas to "take reasonable steps to avoid imposing undue burden" on respondents. Rule 45(c)(3), moreover, expressly "commands that a court 'shall' quash or modify a subpoena if the subpoena 'subjects a person to undue burden.'" *Heidelberg Ams., Inc. v. Tokyo Kikai Seisakusho, Ltd.*, 333 F.3d 38, 41 (1st Cir. 2003). The protection for respondents of subpoenas enshrined in Rule 45 is not discretionary, but instead, "[i]t is a command." *United States v. Amerigroup Illinois, Inc.*, No. 02 C 6074, 2005 U.S. Dist. Lexis 24929, at \*7 (E.D. Ill. Oct. 21, 2005).

In evaluating whether discovery places an "undue burden" on the subpoenaed party, the court must "weigh the burden to the subpoenaed party against the value of the information to the serving party." *Travelers Indem. Co. v. Metro. Life Ins. Co.*, 228 F.R.D.

111, 113 (D. Conn. 2005). The courts are particularly likely to find that a request for information via subpoena constitutes an “undue burden” where, as in this case, the respondent is not a party to the litigation. *See Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1998); *In re: Automotive Refinishing Paint Antitrust Litig.*, 229 F.R.D. 482, 495 (E.D. Pa. 2005); *In re Letters Rogatory Issued by Nat’l Court of First Instance in Comm. Matters*, 144 F.R.D. 272, 278 (E.D. Pa. 1992).

Although discovery is by definition invasive, parties to a law suit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs.

*Cusumano*, 162 F.3d at 717. Additional factors germane to the inquiry include relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described, and the burden imposed. *Travelers Indem. Co.*, 228 F.R.D. at 113; *see In re: Automotive Refinishing Paint Antitrust Litig.*, 229 F.R.D. at 495. Although NHIC must demonstrate that compliance with Defendants’ production request constitutes an undue burden, NHIC easily makes that showing in this case. *Amerigroup Illinois, Inc.*, No. 02 C 6074, at \*7.

**I. DEFENDANTS FAILED TO TAKE REASONABLE STEPS TO AVOID IMPOSING UNDUE BURDEN OR EXPENSE ON NHIC**

Defendants' subpoena seeks the production of 27 discrete categories of documents, spanning a period of more than eight years, from January 1, 1998 through the present. The subpoena seeks documents concerning no less than 130 different "subject drugs." Production of all of the documents sought by Aventis will require a vast deployment of resources, conservatively estimated at this time to total hundreds of thousands of dollars in labor alone, not including the significant expenses of Bates labeling, photocopying, electronic scanning, creation of key-word indexing and retrieval capabilities for review, and shipping. *See* Johnson Aff. ¶ 6. Quite simply, NHIC does not have resources to respond to discovery of the magnitude sought by Aventis in this case.

**A. Responding to the Subpoena Would Impose Unnecessary and Unduly Burdensome Expenses on NHIC.**

As stated in detail in the Affidavit of Deborah A. Johnson, the Massachusetts Systems Support Manager for the Medicare Part B Carrier Account, compliance with the Defendants' subpoena would entail a labor-intensive five-step process that promises to consume thousands of hours of labor, and hundreds of thousands of dollars in expense, simply to identify and gather the potentially responsive documents. *Id.* ¶¶ 4-6. On top of these tasks, NHIC would be required to review these documents for privilege, and to ensure compliance with the strict requirements of HIPAA. *Id.*

To help the Court appreciate the magnitude of Aventis' request for production of documents, NHIC will illustrate the difficulty it would face in responding to just three of Aventis' 27 individual categories of requested documents.

**Defendants' first request for production** seeks "all documents relating to your claims processing policies and procedures for any subject drug in your role as the Medicare Part B Carrier for Massachusetts including, but not limited to, the methodologies considered, rejected, or implemented for calculating Medicare Part B, HCPCS-coded drug reimbursement rates from January 1, 1998 to the present."

To produce its claims processing policies and procedures alone (including both the approximately 960 "desk level procedures" and what are referred to "edits and audits", numbering in the thousands) would require NHIC to conduct a manual search and review to ensure that all current policies and procedures in use by any of its 27 departments were located, and further to review its current edits and audits to determine whether any of the subject drugs is listed for special claims processing. NHIC would also have to conduct a search on the mainframe for "help screen" reports (containing procedural instructions to staff). Next, to obtain superseded procedures that were in effect at some time since January 1, 1998, each NHIC department would have to conduct a search for those documents in its paper and electronic files and off-site storage. Finally, NHIC would have to search electronic mail, paper files, and electronic files for "all documents relating to" those

policies and procedures, such as for example newsletters, postings, and notes of a conference with a provider or customer representative about how a particular policy is being implemented.

**Defendants' second request for production** seeks "[a]ll documents relating to communications to or from CMS or HCFA regarding Medicare Part B reimbursement, payment or prices for any subject drug" from January 1, 1998 to the present.

However, dozens of NHIC's employees (including business analysts, managers, supervisors, and directors) in Massachusetts may have sent communications regarding reimbursement to CMS or HCFA. Therefore, responding to this request would require a manual search through the currently maintained and offsite archives of electronic mail, electronic files, and paper files from a great number of current and former employees and contract workers on NHIC's Medicare Part B Carrier account for Massachusetts.

**Defendants' fifteenth request for production** seeks "[a]ll documents relating to communications to or from providers, benefit consultants or auditors regarding Medicare Part B reimbursement, payment or prices for any subject drug" from January 1, 1998 to the present. As with Request No. 2, this request would cover a vast number of communications, because such communications with providers about reimbursement is a core function performed by NHIC on this account.

**B. Compliance with the Subpoena Would Require NHIC to Dedicate Legal and Administrative Resources to Ensure HIPPA Compliance.**

As noted, many of the documents sought by Defendants contain private medical records. NHIC is required to keep such records confidential pursuant to HIPPA. Review of the records in anticipation of production would, therefore, require a separate and additional analysis by legal counsel.

Defendants have repeatedly attempted to assure NHIC that the Protective Order Governing Confidential Health Information, which applies to the subpoenas directed to NHIC, "obviates any need to review and redact personally identifiable information from documents responsive to [Defendants'] requests." See January 24, 2006 e-mail. However, Defendants' assurances are belied by Section V(C) of the Protective Order, which states:

Notwithstanding any provision of this Order to the contrary, in accordance with any applicable Federal, State, or local laws that afford heightened protection to certain categories of confidential health information, including, but not limited to, records or diagnosis or treatment for alcohol or substance abuse, certain sexually transmitted diseases such as HIV/AIDS, mental health, and research pertaining to genetic testing, *the producing party may completely exclude from production any information afforded heightened protection by such Federal, state, or local laws.*

See Protective Order Governing Confidential Health Information (attached as Exhibit I).

Thus, counsel and administrative staff for NHIC will have to carefully review all of the responsive documents, and evaluate whether any should be withheld from production pursuant to Section V(C) of the Protective Order. At a minimum, counsel and administrative

staff will need to review all responsive documents to ensure compliance with any applicable Federal, State, or local regulations.

**C. Defendants' Offer to Inspect and Copy Documents at Their Own Expense Is Insufficient to Mitigate Undue Burden of Their Subpoena on NHIC**

Defendants' Motion to Compel reflects that Defendants will "inspect and copy documents at their own expense and at the Carriers' respective places of business." Motion to Compel at 7. Defendants' offer to inspect and copy, however, does nothing to mitigate the significant financial burden that would be imposed on NHIC if it is required to comply with the production request sought in Defendants October 27, 2005 subpoena. As set forth in detail in the affidavits submitted in support of NHIC's motion to quash, compliance with Defendants' production request would require NHIC to commit substantial resources to the task of identifying documents that may potentially be responsive to any one of the 27 discrete categories set forth in Defendants' subpoena. *See Johnson Aff.* ¶¶ 4(a)-4(d). In addition, complying with Defendants' request will require NHIC to review all of the responsive documents for privilege, as well as for sensitive health information that is protected by Federal, State, and local law. *Id.* ¶ 5.



**D. This Court Has Recently Granted Motions to Quash Subpoenas Similar in Substance and Scope to That Sought in Defendants' October 27, 2005 Subpoena.**

Defendants' sole legal argument in support of their motion to compel is that this Court has granted Defendants motions to compel in this litigation in the past. Motion to Compel at 7. However, this Court has never granted the Defendants unfettered authority to conduct discovery of non-parties. Indeed, this Court has recently granted several motions for protective orders and motions to quash subpoenas for production of documents and witnesses where, as here, compliance with Defendants' subpoenas for production of documents and witnesses would impose an undue burden on the respondent, and threaten the privacy of health records. On February 2, 2006, this Court heard oral argument on the motions of Fallon Community Health Plan, Inc., Tufts Associated Health Plans, Inc., and Neighborhood Health Plan, Inc., all of which challenged subpoenas for the production of documents similar to the one served on NHIC in this case, and stated: "I feel that the oppressiveness of the burden as has been outlined by counsel for the three health plans is quite dramatic." Transcript, Feb. 2, 2006, at 48 (attached as Exhibit F). The Court ultimately granted the motions to quash, citing its concern for "the rights of non-parties." Similarly, the affidavits filed in support of NHIC's motion to quash the Defendants' October 27 subpoena demonstrate clearly that compliance with the subpoena for document production

would impose an undue burden on NHIC. Here, too, this Court should grant NHIC's motion to quash.

**II. DEFENDANTS DO NOT EVEN ATTEMPT TO ARGUE THAT THEIR NEED FOR THE REQUESTED INFORMATION OUTWEIGHS BURDEN OF PRODUCTION ON NHIC**

Defendants state that the information sought by means of the October 27, 2005 subpoena is "[h]ighly probative," but do not argue that this highly burdensome request for production is *necessary* to prove their case. In particular, they do not even attempt to show that the information they seek cannot be obtained from other sources.

In fact, the Defendants' January 19, 2006 e-mail to NHIC, in which Defendants substantially revised and reduced their request for document production, constitutes strong evidence that Defendants do not need all of the information sought by the October 27, 2005 subpoena. In their January 19, 2006 e-mail to NHIC, counsel for Defendants proposed a revised and substantially reduced production request. If Defendants were willing to settle for the limited request articulated in their January 19, 2006 e-mail, it must be true that not all of the documents originally sought in their original production request are necessary to prove their case.

**CONCLUSION**

For all of these reasons, NHIC respectfully requests that this Court deny Defendants' motion to compel, and grant NHIC's motion to quash Defendants' subpoenas.

Dated: March 17, 2006, Hartford, Connecticut.

**NON-PARTY  
NATIONAL HERITAGE INSURANCE COMPANY**

By: /s/ Benjamin M. Wattenmaker

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**CERTIFICATION**

This is to certify that a copy of the foregoing Non-party National Heritage Insurance Company, Inc.'s Memorandum in Opposition to Defendants' Motion to Compel Production of Documents and Witnesses Pursuant to Subpoenas, and In Support of Its Cross-Motion to Quash Subpoenas, sent via electronic transmission on this 17th day of March 2006, or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

/s/ Benjamin M. Wattenmaker  
Benjamin M. Wattenmaker MA Juris No.:

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